510(k) SUMMARY

DEC 2 7 2012

Sapphire Medical Group, Inc. - A-Wedge Anterior Interbody System

In accordance with 21 CFR 807.92 of the Federal Code of Regulations, the following information is a summary of safety and effectiveness Sapphire Medical Group, Inc.'s A-Wedge Anterior Interbody System.

A. SUBMITTERS INFORMATION

Submitter Name:	BioVera, LLC.
Submitter Address:	815 Iris Lane, Vero Beach, FL 32963
Contact Person:	Robert A Poggie, PhD
Phone Number:	(514) 901-0796; (973) 738-6097
Fax Number:	(514) 901-0796
Date of Submission:	June 1, 2012

B. DEVICE IDENTIFICATION & MANUFACTURER

Manufacturer Name:	Sapphire Medical Group, Inc.
Manufacturer Address:	Sapphire Medical Group, 32565 B Golden Lantern, #113 Dana Point, CA 92629 USA
Registration Number:	To be determined
Contact Name:	Anthony Ruggiero
Title:	President
Device Trade Name:	A-Wedge Anterior Interbody System
Device Common Name:	Intervertebral body fusion device
Classification Name:	Intervertebral body fusion device - lumbar
Classification Code:	MAX – Class II
Classification Panel:	Orthopedic
Regulation Number:	21 CFR section 888.3080

C. PREDICATE DEVICES

K111166	SpineWorks A-Wedge Anterior Interbody System; manufactured by SpineWorks, LLC

D. DEVICE DESCRIPTION

The A-Wedge Anterior Interbody System (A-Wedge AIS) was developed for the stabilization of the lumbar spinal column. The body of the device is a rounded-trapezoidal shape with two large windows allowing placement of bone graft and facilitating fusion. The superior and inferior surfaces of the devices have a pattern of teeth to provide increased stability and inhibit movement of the implants. A-Wedge AIS implants are available in two lordotic configurations (6° and 11°) of various heights to restore lumbar lordosis and the associated sagittal balance. SMG A.I.S. implants have three titanium alloy x-ray markers. The A-Wedge AIS device is single-use only.

Materials: Medical grade PEEK (ASTM F2026) machined from Orthoplastics Vertepeek extruded bar stock (FDA master file MAF #1820). Orthoplastics Vertepeek is fabricated from Evonik Degussa medical grade Vestakeep I PEEK granules (FDA master file MAF # 1688).

ELI grade titanium alloy (Ti-6Al-4V per ASTM F136) for radio opaque markers.

Function: A-Wedge AIS devices are used to maintain disc space distraction in skeletally mature adults requiring intervertebral body fusion.

E. INTENDED USE

The A-Wedge Anterior Interbody System is indicated for intervertebral body fusion procedures in skeletally mature patients with degenerative disc disease (DDD) of the lumbar spine at one or two contiguous levels from L2-S1. Degenerative disc disease is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. These DDD patients may have up to Grade 1 spondylolisthesis or retrolisthesis at the involved level(s). A-Wedge Anterior Interbody System implants are to be used with autogenous bone graft and implanted via an anterior, lateral or anterolateral approach. A-Wedge Anterior Interbody System implants are to be used with supplemental fixation. Patients should have at least six (6) months of non-operative treatment prior to treatment with an intervertebral cage. Patients with previous non-fusion spinal surgery at involved level may be treated with the device.

F. TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE

Subject A-Wedge AIS devices are machined from medical grade extruded PEEK bar stock and fitted with radio opaque markers made from titanium alloy for visualization in radiography. The PEEK and Ti6Al4V materials are intended for permanent implantation. A-Wedge AIS devices are designed to fit the anatomic profile of the lumbar spine. Two lordosis-angle options are offered; 6 and 11 degrees. Height options range from 10 to 18mm, in 2 mm increments. One depth option is offered, 24 mm, and two width options of 26 and 30 mm.

The technological characteristics of Sapphire Medical Group, Inc.'s A-Wedge AIS devices are

identical to the cited predicated device excepting a change in the extruded PEEK bar stock that is used to machine the subject devices. The design, instruments, sterilization, labeling, intended use, size range, and machining processes are identical for the subject device and the cited predicate device. The change in material is as follows: the subject A-Wedge AIS devices are machined from Orthoplastics Ltd. Vertepeek extruded bar and the predicate SpineWork's A-Wedge A.I.S. devices are machined from Invibio PEEK-OPTIMA extruded bar.

Mechanical testing per the FDA Guidance Document for spinal devices and the information contained in Evonik's and Orthoplastic's master files MAF # 1688 and #1820, respectively, show the change in materials for the subject A-Wedge AIS and predicate SpineWork's A-Wedge A.I.S. do not raise new types of safety and efficacy issues; therefore the subject and predicate devices are substantially equivalent.

G. PERFORMANCE DATA

Characterization of A-Wedge AIS devices was performed per the FDA Guidance Document entitled "Class II Special Controls Guidance Document: Intervertebral Body Fusion Device" issued on June 12, 2007. Mechanical testing of the devices was performed per modified version of ASTM standard F2077-03 for static compression, dynamic compression, static compression-shear, and static torsion. Also, ASTM F2267-04 was performed to evaluate subsidence, and draft ASTM standard F04.25.02.02 was performed to evaluate expulsion. All static and dynamic test results met or exceeded the requirements for intervertebral body fusion devices intended for use in the lumbar spine.

H. CONCLUSION

The Sapphire Medical Group A-Wedge Anterior Interbody System is substantially equivalent to the predicate device in terms of indications for use, design, material, performance and function.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

Sapphire Medical Group, Incorporated
% Robert A. Poggie, PhD
BioVera, LLC.
815 Iris Lane
Vero Beach, Florida 32963

Letter dated: December 27, 2012

Re: K121693
Trade/Device Name: A-Wedge Anterior Interbody System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: MAX
Dated: October 19, 2012
Received: October 22, 2012

Dear Dr. Poggie:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K121693

Device Name: A-Wedge Anterior Interbody System

Indications For Use:

The A-Wedge Anterior Interbody System is indicated for intervertebral body fusion procedures in skeletally mature patients with degenerative disc disease (DDD) of the lumbar spine at one or two contiguous levels from L2-S1. Degenerative disc disease is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. These DDD patients may have up to Grade 1 spondylolisthesis or retrolisthesis at the involved level(s). A-Wedge Anterior Interbody System implants are to be used with autogenous bone graft and implanted via an anterior, lateral or anterolateral approach. A-Wedge Anterior Interbody System implants are to be used with supplemental fixation. Patients should have at least six (6) months of non-operative treatment prior to treatment with an intervertebral cage. Patients with previous non-fusion spinal surgery at involved level may be treated with the device.

Prescription Use (Part 21 CFR 801 Subpart D)		AND/OR...	Over-The-Counter Use (21 CFR 801 Subpart C)	
	X			

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH; Office of Device Evaluation (ODE)

Sarah E. Leismer

Division Sign-Off
Division of Orthopedic Devices
510(k) Number: K121693

June 1, 2012